(Attachment)

Partial amendment to the Minimum Requirements for Biological Products and the Public Notice on National Release Testing.

1. The Minimum Requirements for Biological Products

The Article 42, paragraph 1 of Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145, 1955) stipulates that the Minister of Health, Labour and Welfare will establish necessary standards for the manufacturing methods, properties, quality, storage, etc. of drugs after seeking the opinions of Pharmaceutical Affairs Council. Based on this, the standards for manufacturing methods, properties, quality, and storage of biological products such as vaccine and blood products are specified in the Minimum Requirements for Biological Products (Ministerial Notification No. 155 of the Ministry of Health, Labour and Welfare on 2004).

2. The Public Notice on National Release Testing

According to Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, the pharmaceuticals subject to National Release Testing which are designated by Minister of Health, Labour and Welfare (the Public Notice No. 279 of MHW, 1963) has been notified in order to stipulate the pharmaceuticals subject to National Release Testing, fees, criteria and quantities for the testing.

3. The summary of this amendment

The Minimum Requirements for Biological Products will be amended as follows:

・GENERAL RULES

Regarding the standard for "Nasally Live Attenuated Influenza Vaccine", the section of "Attenuation Assay" will be deleted. And the standard for "Purified Typhoid Vi Polysaccharide Vaccine" that is to be newly approved will be added.

・STANDARDS

The section of "Standard Antimeasles Serum" will be partially amended.

The Public Notice on National Release Testing will be amended as follows:

The criterion, fee, and quantity for "Purified Typhoid Vi Polysaccharide Vaccine" that is to be newly approved will be added. And the criterion, fee, and quantity for "Human Serum Albumin" and "Freeze-dried Human Blood Coagulation Factor VIII Concentrate" will be partially amended. In addition, the criterion and fee for "Human Plasma Protein Fraction" will be partially amended.